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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,628	02/23/2004	Joseph P. Errico	F-272	8401
51640 SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090	7590 09/17/2007		EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 09/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/784,628	ERRICO ET AL.
	Examiner	Art Unit
	Jerry Cumberledge	3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 June 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 February 2004 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 04/09/2007.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mauldin (US Pat. 5,732,992).

Mauldin discloses an apparatus for manipulating an orthopedic device (Fig. 3, ref. 99) having first (Fig. 3, near ref. 99) and second baseplates (Fig. 3, near ref. 80), the apparatus comprising: the orthopedic device (Fig. 3, ref. 99) including the first baseplate having a first vertebral body contacting surface (Fig. 3, surface near ref. 99) and the second baseplate having a second vertebral body contacting surface (Fig. 3, surface near ref. 80); at least one shaft (Fig. 3, ref. 60) having a longitudinal axis (Fig. 3) and a shaft distal end (Fig. 3, end near ref. 48) adapted for engagement with the orthopedic device, the shaft distal end further having forward surfaces (Fig. 1A, surfaces of the device which engage ref. 99) for engagement with corresponding confronting surfaces of at least one of the baseplates (Fig. 3, surfaces of ref. 99 shown engaging the device) for axial rotationally aligning the at least one of the baseplates with respect to the longitudinal axis. The device is one of an artificial intervertebral disc, a static trial (column 1, lines 61-67), and a distraction spacer. The forward surfaces of the shaft distal end are flat and angled with respect to one another for mating with the confronting

surfaces of the baseplates (Fig. 3), the confronting surfaces being correspondingly flat and angled (Fig. 3). The forward surfaces are angled with respect to one another at an orientation angle that facilitates engagement of the apparatus with the device in a plurality of rotated positions with respect to the device such that possible engagement orientations approaches include at least an anterior insertion approach and at least one anterior-lateral insertion approach (Fig. 3). The forward surfaces are adapted for engagement with the device such that either an anterior-laterally facing forward surface and an anteriorly facing forward surface is mateable with any of an anterior-laterally facing confronting surface and an anteriorly facing confronting surface (Fig. 3). The anteriorly facing forward surface is spaced from the anteriorly facing confronting surface when two anterior-laterally facing surfaces are engaged with two anterior-laterally facing forward surfaces (Fig. 3). The anteriorly facing forward surface has a length greater than the anteriorly facing confronting surface (Fig. 3). Engagement of at least two of the forward surfaces with at least two of the confronting surfaces significantly limits movement of the at least one of the baseplates relative to the apparatus (Fig. 3). Engagement of at least two of the forward surfaces with at least two of the confronting surfaces substantially minimizes rotation of either of the baseplates about a longitudinal axis of the device (Fig. 3). The apparatus further comprising at least one vertebral body stop (Fig. 3, ref. 40), wherein the stop prevents over-insertion of the device into an intervertebral space (Fig. 3).

Mauldin discloses an apparatus for holding an orthopedic device (Fig. 3, ref. 99), the apparatus comprising: the orthopedic device including a first baseplate (Fig. 3, near

ref. 99) having a first vertebral body contacting surface (Fig. 3, surface near ref. 99) and a second baseplate (Fig. 3, near ref. 80) having a second vertebral body contacting surface (Fig. 3, surface near ref. 80); a shaft (Fig. 3, ref. 60) having a distal end (Fig. 3, end near ref. 48); an extendible and retractable holding pin (Fig. 3, ref. 8) located internal to at least a portion of the shaft distal end (Fig. 4); and a spring (Fig. 3, ref. 54) coupled to the holding pin (Fig. 3) and located internal to at least a portion of the shaft (Fig. 3)(Fig. 4) and biasing the pin toward retraction (column 6, lines 5-14); wherein a holding pin distal end prevents the holding pin from being entirely retracted within the shaft under the bias (Fig. 3); wherein the holding pin engages and disengages a corresponding holding pin device hole (Fig. 3, ref. 80) of the device; wherein the spring spring-loads the holding pin toward at least one shaft distal end surface of the shaft distal end such that when the holding pin is engaged with the corresponding holding pin device hole, the spring spring-loads at least one surface of the device to at least one of the shaft distal end surfaces (column 6, lines 5-14)(Fig. 3). The holding pin extends through the shaft distal end in a direction along a longitudinal axis of the shaft (Fig. 3, Fig. 4). The device comprises the first baseplate and the second baseplate, and wherein the holding pin engages and disengages a corresponding holding pin baseplate hole (Fig. 3, ref. 80) of at least one of the baseplates. The apparatus further comprising a flange (Fig. 1a, ref. 20) mechanically coupled to the holding pin (Fig. 3), wherein exerting pressure on the flange in a distal direction overcomes the bias of the spring to space the holding pin at a distance from the shaft distal end (Fig. 3). The apparatus further comprising a knob (Fig. 3, ref. 42) coupled to the shaft, wherein rotation of the

knob moves the flange such that the holding pin moves closer to the shaft distal end, and wherein reverse rotation of the knob moves the flange such that the holding pin moves away from the shaft distal end (column 7, lines 15-22). The knob is threaded to the shaft (Fig. 3, with threads of ref. 40). Interference between threads of the knob and threads of the shaft lock the holding pin in position. (Fig. 3) The orthopedic device is selected from the group consisting of an artificial intervertebral disc, a static trial (column 1, lines 61-67), and a distraction spacer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mauldin (US Pat. 5,732,992).

Mauldin discloses changing forward surfaces of the device (column 4, lines 39-61).

Mauldin discloses the claimed invention except for the forward surfaces being angled with respect to one another at an orientation angle of approximately 33.4 degrees.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the forward surfaces of Mauldin being angled

with respect to one another at an orientation angle of approximately 33.4 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mauldin (US Pat. 5,732,992 in view of Michelson (US Pub. 2002/0177897 A1).

Mauldin discloses that the device is usable to grasp and securely retain prosthesis implant and trial pieces of varied sizes and geometries (column 1, lines 61-67).

Mauldin does not disclose an orthopedic device which is joined by a central coupling that enables the first and second baseplates to rotate and angulate relative to one another.

Michelson discloses an apparatus for manipulating an orthopedic device (Fig. 26, ref. 500) that is used in tandem with an orthopedic device (Fig. 26, ref. 100) which is joined by a central coupling (Fig. 26)(Fig. 152, 154) that enables the first and second baseplates to rotate and angulate relative to one another (Fig. 26 and Fig. 31). The apparatus is used to hold and manipulate the implant during insertion into the disc space (paragraph 0120).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the orthopedic device of Mauldin with the orthopedic device of Michelson to achieve the predictable result of grasping and manipulating an orthopedic device with an apparatus.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER